



Translation

## PATENT COOPERATION TREATY

PCT

Rec'd PCT/PTO 09 JUN 2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|  |   |   |                       |
|--|---|---|-----------------------|
| Applicant's or agent's file reference<br><b>P03-133</b>  | <b>FOR FURTHER ACTION</b>   |   | See Form PCT/IPEA/416 |
| International application No.<br><b>PCT/JP2003/015828</b>  | International filing date ( <i>day/month/year</i> )<br><b>11 December 2003 (11.12.2003)</b> | Priority date ( <i>day/month/year</i> )<br><b>12 December 2002 (12.12.2002)</b> |                       |
| International Patent Classification (IPC) or national classification and IPC<br><b>C07K 19/00, C12N 15/62, C12Q 1/37</b> |   |   |                       |
| <b>Applicant</b><br><b>NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY</b>                              |   |   |                       |

|   |
|---|
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>3</u> sheets, as follows:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input checked="" type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) <u>DISC 1</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input checked="" type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul> |
|---|

|   |  |
|---|--|
| Date of submission of the demand<br><b>11 May 2004 (11.05.2004)</b> | Date of completion of this report<br><b>14 January 2005 (14.01.2005)</b> |
| Name and mailing address of the IPEA/JP                             | Authorized officer   |
| Facsimile No.   | Telephone No.  |

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/015828

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

The international application as originally filed/furnished

the description:

pages 1-16, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

pages 4-6,8,11,12,14,15,17, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* 1,9,13,16,18-21 received by this Authority on 13 October 2004 (13.10.2004)

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

pages 1-5, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_

the claims, Nos. 2,3,7,10

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_

the claims, Nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (*specify*): \_\_\_\_\_

any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/15828

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

|                               |        |                     |     |
|-------------------------------|--------|---------------------|-----|
| Novelty (N)                   | Claims | 1, 4-6, 8, 9, 11-21 | YES |
|                               | Claims |                     | NO  |
| Inventive step (IS)           | Claims | 1, 4-6, 8, 9, 11-21 | YES |
|                               | Claims |                     | NO  |
| Industrial applicability (IA) | Claims | 1, 4-6, 8, 9, 11-21 | YES |
|                               | Claims |                     | NO  |

**2. Citations and explanations (Rule 70.7)**

Document 1: Uehara Memorial Foundation Kenkyu Hokokusho 2002, Nov., Vol. 16, p. 257-259

The inventions of claims 1, 4-6, 8, 9, and 11-21 are novel and involve an inventive step with respect to the documents cited in the international search report.

Document 1 describes the expression of a chimeric protein comprising *Renilla luciferase*-nocistatin/nociseptin-green fluorescent protein (GFP) in COS cells, and it states that the luminescence differs depending on the presence or absence of processing of this chimeric protein (Figure 1, etc.) However, it does not describe preparing the fusion protein into a secreted form by making the luciferase into the secreted form of luciferase or a non-secreted form of luciferase with a secretion protein ligated to its N-terminus. On the other hand, the invention of this application provides the advantageous effect of "making it possible to monitor processing without destruction of the cell by enabling measurement of the luminescence spectrum of the liquid culture medium."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/15828

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

| Application No.<br>Patent No. | Publication date<br>(day/month/year) | Filing date<br>(day/month/year) | Priority date (valid claim)<br>(day/month/year) |
|-------------------------------|--------------------------------------|---------------------------------|---|
| WO 2004/022600 A1             | 18.03.2004                           | 04.09.2003                      | 06.09.2002                                      |

[E,X]

## 2. Non-written disclosures (Rule 70.9)

| Kind of non-written disclosure | Date of non-written disclosure<br>(day/month/year) | Date of written disclosure<br>referring to non-written disclosure<br>(day/month/year) |
|--------------------------------|--|---|
|                                |  |   |

**Supplemental Box Relating to Sequence Listing****Continuation of Box No. 1, item 2:**

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

## a. type of material

a sequence listing  
 table(s) related to the sequence listing

## b. format of material

in written format  
 in computer readable form

## c. time of filing/furnishing

contained in the international application as filed  
 filed together with the international application in computer readable form  
 furnished subsequently to this Authority for the purpose of search and/or examination  
 received by this Authority as an amendment\* on \_\_\_\_\_

2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

\* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".